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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,848	09/15/2003	Claudia Cherney Stewart	JG-RP-4796CIP-C/500561.20	1191

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REED SMITH, LLP  
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NEW YORK, NY 10022-7650

EXAMINER
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WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/662,848	<b>Applicant(s)</b> STEWART, CLAUDIA CHERNEY	
	<b>Examiner</b> Shengjun Wang	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 22-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's election without traverse of group II, and the compound 96 as the elected species in the reply filed on June 28, 2007 is acknowledged.
2. On further consideration, particularly, in view of the office action set forth in the parent application, the restriction requirements in the prior office action is withdrawn as the two alleged invention are not independent and distinct each from the others. The species elections requirement is maintained.
3. The claims have been examined insofar as they read on the elected species.

#### *Claim Rejections 35 U.S.C. 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim interpretation: During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See *In re Morris*, 127 F.3d 1048, 44

USPQ2d 1023 (Fed. Cir. 1997). See MPEP § 2111 - § 2116.01 for case law

pertinent to claim analysis. Claims 1-11, 22-26, 28, 33-35 are interpreted as it encompass prophylactic treating a subject for viral infection thereby reduce the risk of infection and preventing or protecting a subject from the viral infection.

5. Claims 27, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. Claims 27 and 30-32 drawn to “a method of treating a subject *infected* with a papillomavirus or an adenovirus”. The application as originally filed lack support for treating a subject infected with the virus. The application provides method of prophylactic treatment of a subject against infection of the virus, but fails to describe a method of treating an infected subject.

6. Claims 1-11 and 22-26, 28, 33-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prophylactic treatment of a viral infection thereby reducing the risk of infection, does not reasonably provide enablement for complete prophylaxis against, or protection from the papillomaviurs or adenovirus infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factor to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the art, the relative skill of those in the art, the predictability of the art and the breadth of the claims. In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988). The specification and the prior art (Dori) reveal that the compounds herein are effective for treating viral infection. Specifically, the compounds herein “at the cellular sites of infection which are sufficiently in excess of those concentration necessary to inhibit virus replication and/or abort the virus’s effective life cycle.” (Dori). The specification herein shows that the compound is useful for reducing the activity of viral infections. See pages 26-32). However, the application provide no further guidance or direction as to prophylaxis

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against, or protect from, the infections of the virus. Although one would like to prophylaxis against, or protected from viral infection, numerous factors are associated with viral infection, such that the prior art and the instant specification fail to enable the prophylaxis against viral infections, but do enable prophylactic treatment supporting "reducing the risk of transmission of the viral or reduce the viral activity of the infection. It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity. It is particularly true for art related to viral infection. Prevention, or prophylaxis of viral infection in general remains challenge to the skilled artisan. Limited successful examples of prophylaxis against viral infections are all by vaccination. The employment of small organic molecules for preventing viral infection is unpredictable. The court in *In re Fisher*, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) held that, "in case involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." The more unpredictable an area, the more specific enablement is need in order to satisfy the statue. The Unpredictability is more apparent where the diseases disclosed in the specification are as complex and diverse in etiology. In the instant case, that art does have product available for successful prophylaxis of viral infection with small organic molecules, but the art and the evidence presented in the instant application fails to establish support for prophylaxis against, or protected from, viral infection as instantly claimed. Thus it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 recite a formula. However, A, B, Y, X and Z- in the formula, have not been clearly defined. The claims are indefinite as to the compounds employed in the method.

### ***Double Patenting Rejections***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-9, 11-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 41-53 of copending Application No. 09/330629. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of '629 are directed to prophylactically reducing the risk of

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transmission of HIV. Claims herein are directed to prophylactically reducing the risk of transmission of "a specific virus." Therefore the claims herein are generic to the claims in '629

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections 35 U.S.C. 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-12, 22-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dori (US 5,756,491), in view of Field's Virology.

14. Dori teaches an antiviral method comprising administering to a subject having a disease caused by viral infection an antiviral effective amount of the compound herein. See, particularly, the claims. Compound 96 is disclosed in col. 4. Dori further teaches that

The inventive compounds and compositions may be used in treating infections caused by a variety of viruses. Certain compounds within the group may exhibit greater efficacy against specified viruses as compared with other compounds within the inventive group. Accordingly, the present invention includes the inventive compositions wherein the composition contains a compound as defined herein above in an amount which is effective against the specific virus being treated. Known *viruses of clinical significance* are disclosed in Stedman's Medical Dictionary, 24th Ed., Williams & Wilkins, pp. 1559-1565, (1982); **Virology, B. N. Fields, D. M. Knipe, R. M. Chanock, J. L. Melnick, & R. E. Shope, Raven Press, N.Y. (1985).** See also Antiviral Agents and Viral Diseases of Man, George J. Galasso, Richard J. Whitley, and Thomas C. Meriyan, Ed., Third Edition, 1990, Raven Press, N.Y. (col. 5, line 59 to col. 6, line 7, emphasis added).

Dori teaches that the compounds as antiviral agents may be administered by conventional routes, such as oral, parenteral, and topical administration. See, particularly, col. 6, lines 10-43.

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Dori teaches employing the claimed compounds “at the cellular sites of infection which are sufficiently in excess of those concentration necessary to inhibit virus replication and/or **abort** the virus’s effective life cycle.” (emphasis added). Col. 5, line 55-58.

Dori does not teach expressly prophylactic treatment, or for the particular viral herein.

However, papillomavirus and adenovirus are listed as human pathogens by Field’s Virology. See, pages 26.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the compounds disclosed by Dori, such as compound 96 for treating or prophylactic treating the particular viral agents herein.

A person of ordinary skill in the art would have been motivated to use the compounds disclosed by Dori, such as compound 96 for treating or prophylactic treating the particular viral agents herein because Dori teaches the compound as useful broadly for treating viral etiological agents. To ascertain those viral agents the skilled artisan is directed to Fields Virology for a listing of pathogens. Those viral agents taught by Dori, residing in Field’s Virology, recite the etiological agents herein claimed. Thus, the skilled artisan would have been motivated by the teaching of Dori to employ the compounds herein against the instant viral agents and enjoy a reasonable expectation of therapeutic success.

As to the “prophylactic treatment”, note it is generally considered prima facie obvious to employ therapeutic compounds prophylactically. In the instant case the motivation for prophylactic use flows from Dori teaching employing the claimed compounds “at the cellular sites of infection which are sufficiently in excess of those concentration necessary to inhibit virus replication and/or **abort** the virus’s effective life cycle.”



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As to the particular method of administering the compounds and the timing of the administration, note Dori teaches the compounds may be administered by various conventional method, including oral, parenteral, and topical administration. Therefore, the employment of compound in conventional forms, such as oral composition or topical composition would have been within the purview of skilled artisan. Furthermore, the optimization of a result effective parameter, effective amount of a therapeutic agent or the timing for administering the agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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